Complete Summary

GUIDELINE TITLE

Urinary incontinence in women.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Urinary incontinence in women. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2008 Aug 8 [Various].

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. Urinary incontinence in women. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2005 Aug 31 [Various].

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 22, 2008, Surgical mesh devices: The U.S. Food and Drug Administration (FDA) informed healthcare professionals of serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). The FDA provided recommended actions for both physicians and patients to reduce the risks.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Urinary incontinence, including:

- Stress incontinence
- Urge incontinence
- Mixed incontinence
- Overflow incontinence

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Surgery
Urology

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Women with urinary incontinence

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Diagnosis

1. Determining type of incontinence: stress, urge, mixed, overflow

2. History related to incontinence
3. Clinical examination
    - General examination
    - Gynecological examination

4. Laboratory investigations and imaging studies
    - Urine chemistry
    - Microscopic examination for hematuria
    - Urine culture
    - Cytological examination of urine
    - Cystoscopy
    - Urinary tract ultrasonography

5. Referral to a specialist when indicated

Treatment/Management

1. Conservative treatment
    - Lifestyle changes: weight loss, fluid restriction if indicated, treatment of constipation
    - Pelvic floor muscle training
    - Physiotherapy
    - Electrical stimulation

2. Pharmacotherapy for urge incontinence
    - Oestrogen therapy
    - Anticholinergic drugs: oxybutynin, tolterodine, trospium chloride, solifenacin and darifenacin

3. Surgical treatment
    - Mini-invasive suburethral sling procedures for stress incontinence
        - Tension-free vaginal tape
        - Transobturator tape procedures
    - Intradetrusor injection of botulinum toxin
    - Sacral nerve root neuromodulation
    - Augmentation cystoplasty

4. Incontinence protection products

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Subjective cure
- Side effects of medications
- Surgical complication rates
- Cost effectiveness
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification of the Quality of Evidence

Code	Quality of Evidence	Definition
A	**High**	Further research is very unlikely to change our confidence in the estimate of effect. • Several high-quality studies with consistent results • In special cases: one large, high-quality multi-centre trial
B	**Moderate**	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate. • One high-quality study • Several studies with some limitations
C	**Low**	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate. • One or more studies with severe limitations
D	**Very Low**	Any estimate of effect is very uncertain.

Code	Quality of Evidence	Definition
		• Expert opinion • No direct research evidence • One or more studies with very severe limitations

GRADE (Grading of Recommendations Assessment, Development and Evaluation) Working Group 2007 (modified by the EBM Guidelines Editorial Team).

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Tension-Free Vaginal Tape (TVT)

A technology assessment report summarizes in a systematic review that laparoscopic colposuspension and traditional slings have broadly similar cure rates to TVT and open colposuspension, whereas injectable agents appear to have lower cure rates. TVT is less invasive than colposuspension and traditional sling procedures, and is also usually performed under regional or local anaesthesia. The principal operative complication is bladder perforation. Long-term effects (>2 years) are currently not known reliably. TVT was more likely to be considered cost-effective compared with the other surgical procedures.

Another technology assessment report summarizes in a systematic review that the surgical component of TVT is more expensive than colposuspension. However, there is a cost-saving per patient when accounting for the higher number of hospital bed-days associated with recovery from more invasive surgery. Perioperative complication rates of TVT have earlier been higher than in colposuspension, but in more recent studies complication rates are lower, perhaps owing to the greater experience of surgeons.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

Aim

- It is important to differentiate stress incontinence from other types of incontinence which may also be caused by different treatable gynaecological, urological or neurological illnesses.

Types of Incontinence

1. In **stress incontinence**, involuntary loss of urine occurs during physical exertion or strain (e.g., coughing or sneezing), and it affects approximately three quarters of adult patients who present with incontinence.
2. **Urge incontinence** is characterised by a sudden urge to urinate followed by involuntary loss of urine, either during the urge or immediately afterwards. It is typically seen in elderly post-menopausal women and also in young women.
3. **Mixed incontinence** is a combination of the two above types. It is most common in women aged over 70 years.
4. Incomplete voiding and urinary retention, whether acute or chronic, may lead to **overflow incontinence**.

Epidemiology

- In epidemiological studies, the prevalence of female urinary incontinence in the adult population has ranged between 5% and 58% (median 28% [Cheater & Castleden, 2000]). More than 50% of patients conceal the problem.
- Approximately 6% of the population suffers from urinary incontinence of sufficient severity to interfere with their quality of life.
- Urinary incontinence increases in frequency with age. Around 60% of women over 70 years of age suffer from it.

Aetiology

- **Stress incontinence** is caused by weakness of the structures supporting the urethra or by sphincter insufficiency. The risk factors for stress incontinence include obesity (>20%), pregnancy and giving birth as well as heavy

smoking. Congenital connective tissue weakness may also be a risk factor for stress incontinence.

- In **urge incontinence** bladder muscles contract inappropriately, the cause of which may be
    - Neurogenic (multiple sclerosis [MS], dementia, disturbances in cerebral circulation, Parkinson's disease, diabetes)
    - Non-neurogenic (acute or recurrent urinary tract infection, history of complicated urinary tract infections, tumour, disease affecting the bladder wall, bladder calculus, local oestrogen deficiency in postmenopausal women, fast bladder filling, diuretics, hysterectomy (Brown et al., 2000; Altman et al., 2007) **[C]**
    - Idiopathic; in approximately 80% of cases the cause remains unknown.
- **Overflow incontinence** is caused either by impaired micturition reflex (e.g., a neurogenic aetiology, post surgery, a drug adverse effect) or by a mechanical obstruction (tumour, prolapse).

Investigations

History

- In what situations does incontinence occur?
    - Standardised symptom questionnaires are suitable for clinical practice.
- For how long has incontinence lasted?
    - Moderately severe urge incontinence with a fairly sudden onset may be suggestive of an organic aetiology, e.g., bladder disease, inflammation or pelvic tumour.
- Severity?
    - How many times a week does the patient experience urinary incontinence, does she need to use protective pads and what impact does incontinence have on her life?
- A frequency/volume chart is a simple tool for monitoring bladder function and the type and severity of incontinence.
- Gynaecological history: deliveries, surgery, menstrual cycle
- Systemic illnesses and medication that may potentially affect bladder function (diuretics, anticholinergics)

Clinical Examination

- General clinical examination: general health status, mobility, weight, neurological abnormalities.
- Gynaecological examination: mucous membranes, prolapses, palpation to exclude tumours, cough stress test and measurement of residual urine ([see the Finnish Medical Society Duodecim guideline "Determining the volume of residual urine by ultrasonography") in case of incomplete voiding.

Laboratory Investigations and Imaging Studies

- In case of urge incontinence or mixed incontinence, urine chemistry should be carried out and, if indicated, microscopic examinations and culture.
    - Occasional microscopic haematuria may be associated with physical exercise, menstruation, sexual intercourse or minor trauma.

- Recurrent microscopic haematuria ([see the Finnish Medical Society Duodecim guideline "Hematuria". Note; a reagent strip test alone is not sufficient) warrants a cytological examination of the urine, cystoscopy and urinary tract ultrasonography.

Indications for a Referral to Specialist Care

- Haematuria or a suspicion of a bladder disease (interstitial cystitis, bladder calculus, bladder cancer)
- Residual urine volume more than 100 mL (measured if the patient has difficulties passing urine or if overflow incontinence is suspected)
- Symptomatic prolapse
- Pelvic tumour
- Neurological problems
- Troublesome incontinence that has already been treated with surgery
- Suspicion of a fistula
- Treatment-resistant urge incontinence
- Stress incontinence if physiotherapy fails to provide adequate relief
- Problems in differential diagnosis

Conservative Treatment

- Lifestyle changes may alleviate both urge and stress incontinence.
    - Weight loss (5% to 10%) alleviates incontinence symptoms and improves the quality of life.
    - Fluid restriction is recommended only if daily fluid intake exceeds 3,000 mL.
    - Treatment of constipation
- Pelvic floor muscle training and physiotherapy:
    - Supervised regular pelvic floor muscle training of 2–6 months' duration is an effective form of therapy for all types of urinary incontinence (Hay-Smith & Dumoulin, 2006; Berghams et al., 2000; de Kruif & van Wegan,1996) **[A]**.
    - Pelvic floor muscle training is also beneficial in postpartum incontinence (Hay-Smith et al., 2008) **[A]**.
    - If the outcome of self-directed training is not satisfactory after 2 months, the patient should be referred to an appropriately trained physiotherapist.
- Electrical stimulation in order to reduce the overactivity of the bladder muscle (Bo, 1998) **[D]** as well as bladder training (Wallace et al., 2004; Berghams et al., 2000) **[C]** may also be employed in urge incontinence.

Pharmacotherapy

- Stress incontinence: drug therapy only plays a minor role
- Urge incontinence
    - Local oestrogen therapy appears to cure or alleviate symptoms in postmenopausal women (Moehrer, Hextall, & Jackson, 2003; Fantl, Cardozo, & McClish, 1994; Zullo et al., 1998) **[B]**. Bladder irritation will reduce as urogenital atrophy reverses and urinary tract infections reduce in number. The patient should be informed that itching and burning may occur at the beginning of treatment.

- Anticholinergic drugs are used widely in the treatment of urge incontinence (Nabi et al., 2006; Alhasso et al., 2006) **[A]**. Drugs in this group include oxybutynin, tolterodine, trospium chloride, solifenacin and darifenacin.
    - Contraindications: urinary retention, uncontrolled narrow-angle glaucoma, myasthenia gravis, severe colitis.
    - Interactions must be borne in mind.
    - The most common adverse effects: dry mouth, blurred vision, postural hypotension, constipation and urinary retention. Moreover, the patient may experience central nervous system effects, such as cognitive disorders and confusion, which may be particularly troublesome in elderly patients.
    - The efficacy of the medication should be assessed at regular intervals (after about 2 months) because only a proportion of patients will benefit from the treatment and, on the other hand, if the adverse effects are only mild a dose increase may be attempted.
    - There is no difference in efficacy between the different agents. Adverse effect profiles are individual: try different preparations.

Surgical Treatment

- Should conservative treatment not yield adequate response stress incontinence may be treated surgically, if considered appropriate by a urogynaecologist.
    - Mini-invasive suburethral sling procedures are effective (Bezerra, Bruschini, & Cody, 2005; Valpas et al., 2004; Ward & Hilton, 2004; Paraiso et al. 2005; Cody et al., 2003; "Tension-free vaginal tape," 2004) **[A]** and can be carried out under local anaesthesia.
        - Tension-free vaginal tape (TVT) made of polypropylene mesh may be inserted retropubically underneath the midurethral region.
        - In transobturator tape procedures (TOT, TVT-O) the mesh is tunnelled from the vaginal side to the top of the thigh or vice versa.
        - At the postoperative check-up the patient must be checked for urinary retention, retropubic haematoma (usually resorbs spontaneously), poor healing of the vaginal incision or visible tape ends.
        - In pure stress incontinence the long-term outcome is good (at a 7-year follow-up 81% of the patients were continent) (Nilsson, Falconer, & Rezapour, 2004).
        - In mixed incontinence the results are poorer (Holmgren et al., 2005).
- Surgery is of no help in pure urge incontinence. In extreme cases, intradetrusor injections of botulinum toxin A (Duthie et al., 2007) **[D]**, sacral nerve root neuromodulation or augmentation cystoplasty may be considered.
- The treatment for mixed incontinence is chosen according to the dominant type of incontinence.

Incontinence Protection

Absorbent pads, pants and protective bedding will provide protection. Vaginal cones and tampons prevent incontinence during short-lasting physical exercise. A trained incontinence nurse will be in charge of patient education and supplying incontinence products.

Related Evidence

Refer to the original guideline document for related evidence, including Cochrane reviews and other evidence summaries.

Definitions:

Classification of the Quality of Evidence

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline may help the clinician differentiate between types of incontinence in women and select appropriate interventions to reduce or eliminate symptoms of urinary incontinence.

Subgroups Most Likely to Benefit

Postmenopausal women are most likely to benefit from oestrogen therapy.

POTENTIAL HARMS

- The patient should be informed that itching and burning may occur at the beginning of estrogen treatment.
- The most common adverse effects of anticholinergic drugs are: dry mouth, blurred vision, postural hypotension, constipation and urinary retention. Moreover, the patient may experience central nervous system effects, such as cognitive disorders and confusion, which may be particularly troublesome in elderly patients.
- Drug interactions with anticholinergic drugs must be borne in mind.
- At the postoperative check-up after mini-invasive suburethral sling procedures, the patient must be checked for urinary retention, retropubic haematoma (usually resorbs spontaneously), poor healing of the vaginal incision or visible tape ends.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to anticholinergic drug therapy include urinary retention, uncontrolled narrow-angle glaucoma, myasthenia gravis, and severe colitis.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Urinary incontinence in women. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2008 Aug 8 [Various].

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 4 (revised 2008 Aug 8)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Beata Stach-Lempinen

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. Urinary incontinence in women. In: EBM Guidelines. Evidence-Based Medicine [Internet]. Helsinki, Finland: Wiley Interscience. John Wiley & Sons; 2005 Aug 31 [Various].

GUIDELINE AVAILABILITY

This guideline is included in "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 17, 2002. The information was verified by the guideline developer as of February 7, 2003. This summary was updated by ECRI on April 2, 2004, October 5, 2004, February 22, 2005, June 10, 2005, and November 3, 2005. This summary was updated by ECRI on March 8, 2006, following the U.S. Food and Drug Administration advisory on Cymbalta (duloxetine hydrochloride). This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on January 9, 2009.

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Date Modified: 3/9/2009